NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

2008-1225

NOVO NORDISK A/S,

Plaintiff-Appellant,

v.

SANOFI-AVENTIS U.S. LLC and SANOFI-AVENTIS DEUTSCHLAND GMBH,

Defendants-Appellees,

and

SANOFI-AVENTIS,

Defendant.

<u>David B. Tulchin</u>, Sullivan & Cromwell, LLP, of New York, New York, argued for plaintiff-appellant. With him on the brief were <u>Marc De Leeuw</u> and <u>James T.</u> <u>Williams</u>.

<u>Paul H. Berghoff</u>, McDonnell Boehnen Hulbert & Berghoff, LLP, of Chicago, Illinois, argued for defendants-appellees. With him on the brief were <u>David M.</u> <u>Frischkorn</u>, <u>Curt J. Whitenack</u>, and <u>Eric R. Moran</u>.

Appealed from: United States District Court for the District of New Jersey

Judge Mary L. Cooper

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SANOFI-AVENTIS U.S. LLC and SANOFI-AVENTIS DEUTSCHLAND GMBH,

Defendants-Appellees,

and

SANOFI-AVENTIS,

Defendant.

Appeal from the United States District Court for the District of New Jersey in case no. 07-CV-3206, Judge Mary L. Cooper.

DECIDED: July 30, 2008

Before LOURIE, BRYSON, and PROST, Circuit Judges.

PROST, Circuit Judge.

Plaintiff-Appellant Novo Nordisk A/S ("Novo") sued Defendants-Appellees Sanofi-

Aventis U.S. LLC, Sanofi-Aventis, and Sanofi-Aventis Deutschland GmbH (collectively

"Sanofi"), alleging that Sanofi's SoloStar product infringes one or more claims of Novo's

U.S. Patent No. 7,241,278 (the "278 patent"). Novo then filed a motion to preliminarily

enjoin Sanofi "from making, using, selling, offering to sell, and/or importing SoloStar in

the United States." The United States District Court for the District of New Jersey denied Novo's request for a preliminary injunction, <u>Novo Nordisk A/S v. Sanofi-Aventis</u> <u>U.S. LLC</u>, 3:07-CV-3206, slip op. (D.N.J. Feb. 19, 2008) ("<u>Injunction Order</u>"), and Novo appealed. Having jurisdiction pursuant to 28 U.S.C. §§ 1292(c)(1) and 1295(a)(1), we <u>affirm</u>.

DISCUSSION

In order to obtain a preliminary injunction, a patentee must show: "(1) reasonable likelihood of success on the merits; (2) irreparable harm; (3) that the balance of hardships tips in its favor; and (4) the impact of the injunction on the public interest." Jack Guttman, Inc. v. Kopykake Enters., 302 F.3d 1352, 1356 (Fed. Cir. 2002). The denial of a preliminary injunction pursuant to 35 U.S.C. § 283 is within a district court's discretion. <u>Genentech, Inc. v. Novo Nordisk A/S</u>, 108 F.3d 1361, 1364 (Fed. Cir. 1997). We will reverse such a decision only when an appellant demonstrates that the "factors relied on by the district court [were] clearly erroneous" and "that a denial of the preliminary relief sought would amount to an abuse of the court's discretion upon reversal of an erroneous finding." <u>New Eng. Braiding Co. v. A.W. Chesterton Co.</u>, 970 F.2d 878, 882 (Fed. Cir. 1992).

In this case, the district court denied the preliminary injunction because the patentee failed to show a reasonable likelihood of success on the merits. <u>Injunction</u> <u>Order</u> at 38. The court concluded, "Novo has not shown that Sanofi's asserted defense that SoloStar does not infringe the '278 patent because it lacks direct gearing and a non-rotatable piston rod, lacks substantial merit." <u>Id.</u> The district court reasoned that Sanofi "raised substantial questions regarding whether the specification read as a whole

2

suggests that the very character of the invention requires direct gearing and a nonrotatable piston rod to be part of every embodiment." <u>Id.</u> at 35. These substantial questions included:

whether (1) the embodiments of the invention set forth in the specification as "the invention" constitute the invention itself despite claim language that could be interpreted more broadly, (2) the specification expressly disclaims injection pens with rotating piston rods or gearing other than direct gearing, (3) the specification suggests the need to narrowly construe the claims because it distinguishes prior art or clearly expresses an intention to limit the invention's structure, and (4) Novo's amendment of the '278 patent's claims to import language from the DCA Application affects this Court's use of the specification, which was not amended, in construing such claims (<u>i.e.</u>, whether the Court should ignore the specification and assume that Novo abandoned the gearbox in favor of the clutch mechanism when it amended its claims to import claims from the DCA Application).

<u>Id.</u> at 36. The district court ultimately found that these substantial questions precluded a finding that Novo has a likelihood of success on the merits and, accordingly, denied Novo's motion for a preliminary injunction. <u>Id.</u> at 38, 40.

Novo appeals, arguing that the district court erred in interpreting the claims to require a gearbox and non-rotating piston rod. Novo asserts that the district court's claim construction is legal error because the claim language is clear, the specification contains no disclaimer, the prosecution history makes clear that Novo abandoned these requirements, and the doctrine of claim differentiation supports Novo's proposed construction. In response, Sanofi asserts that the specification mandates that the claimed injection device include a gearbox and non-rotatable piston rod. Sanofi also argues that the specification barely refers to a "clutch," which Novo asserts is the crucial component of its independent claims. Further, Sanofi contends that the injection device described by the '278 patent could not function without the gearbox and non-rotatable

piston rod. Accordingly, Sanofi asserts that the district court correctly construed the claims.

After reviewing the intrinsic record, we cannot conclude that the district court abused its discretion. The district court found that a question exists regarding whether "the very character of the invention requires direct gearing and a non-rotatable piston rod," <u>id.</u> at 35, a finding which, at this stage of the proceedings and on this record, we do not view to be clearly erroneous. Although Novo argues that the claims do not explicitly include the terms "gearbox" or "non-rotatable piston rod," Sanofi notes that the specification is directed to an invention that appears to center on the "gearbox" and "non-rotatable piston rod" components. In light of this apparent conflict between the specification and the claims, the district court appropriately exercised its discretion in concluding that Novo has not established a likelihood of success on the merits.

Moreover, notwithstanding Novo's arguments to the contrary, we read the district court's opinion as generally addressing whether Sanofi raised "substantial questions," rather than specifically articulating a claim construction. While it is true that many of the substantial questions identified by the district court would ultimately be analyzed in the context of construing the claims, some might more appropriately be analyzed in the context of validity (i.e., written description and enablement). <u>See, e.g., Tate Access</u> <u>Floors, Inc. v. Interface Architectural Res., Inc.</u>, 279 F.3d 1357, 1372 (Fed. Cir. 2002) ("[W]here claim language is clear we must accord it full breadth even if the result is a claim that is clearly invalid."). At the preliminary injunction stage, however, it is irrelevant whether this case presents greater issues of claim construction or validity—the existence of one or both of these issues is sufficient to justify the district court's

4

decision to deny a preliminary injunction. As this court previously explained in a similar

situation:

Cases such as this one, in which predecessor applications or patents were drawn to narrow claims and in which the claims in the successor application are arguably broader than the invention described in the specification, present difficult questions of both claim construction and validity. Where the applicant expressly and unambiguously states his intention to claim broadly, the claim construction issue is easier and the question becomes one of validity-whether the specification supports the full breadth of the new claims. On the other hand, where—as in this case-the patentee has not been explicit about the scope of the new claims, the case can pose interdependent problems of both claim construction and validity.

Saunders Group, Inc. v. Comfortrac, Inc., 492 F.3d 1326, 1335-36 (Fed. Cir. 2007).

CONCLUSION

The record is sufficient to support the district court's finding that Novo has not

shown a likelihood of success on the merits. Accordingly, we conclude that the district

court did not abuse its discretion in denying Novo's motion for a preliminary injunction.